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Request for Continued Examination (RCE) Transmittal

Address to:
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Application Number	10/008,223
Filing Date	12/05/2001
First Named Inventor	Xiaorong Ho
Art Unit	1617
Examiner Name	Yong Soo Chong
Attorney Docket Number	C-3409/1/US (031297)

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. See Instruction Sheet for RCEs (not to be submitted to the USPTO) on page 2.

1. Submission required under 37 CFR 1.114 Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

   a. ☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

      i. ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____

      ii. ☐ Other _____

   b. ☑ Enclosed

      i. ☑ Amendment/Reply

      ii. ☐ Affidavit(s)/ Declaration(s)

      iii. ☐ Information Disclosure Statement (IDS)

      iv. ☐ Other _____

2. Miscellaneous

   a. ☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of _____ months. (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

   b. ☐ Other _____

3. Fees The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.

   a. ☑ The Director is hereby authorized to charge the following fees, any underpayment of fees, or credit any overpayments, to Deposit Account No. 19-1025. I have enclosed a duplicate copy of this sheet.

      i. ☑ RCE fee required under 37 CFR 1.17(e)

      ii. ☑ Extension of time fee (37 CFR 1.136 and 1.17)

      iii. ☐ Other _____

   b. ☐ Check in the amount of $ _____ enclosed

   c. ☐ Payment by credit card (Form PTO-2038 enclosed)

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

Signature	Patricia K. Fitzsimmons	Date	June 8, 2006
Name (Print/Type)	Patricia K. Fitzsimmons	Registration No.	52,894

CERTIFICATE OF MAILING OR TRANSMISSION

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450 or facsimile transmitted to the U.S. Patent and Trademark Office on the date shown below. N/A Electronic Filing

Signature	Linda K. Cooper		
Name (Print/Type)	Linda K. Cooper	Date	June 8, 2006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT:	He	GROUP ART UNIT:	1617
SERIAL NO.:	10/008,223	CONFIRMATION NO.:	4333
EXAMINER:	Webman	ATTORNEY DOCKET NO.:	3409/1/US (PC31297)
FILED:	December 5, 2001		

TITLE: RAPIDLY DISPERSING PHARMACEUTICAL COMPOSITION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

June 8, 2006

AMENDMENT B

Sir:

In response to the Office action dated December 8, 2005, the time for response to which has been extended by three (3) months, please amend the above-identified application as follows:

Amendments to the Claims are reflected in the listing of claims that begins on page 2 of this paper.

Remarks/Arguments begin on page 6 of this paper.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claims 1-17 (cancelled).

Claim 18 (currently amended): A solid pharmaceutical composition **that is a dosage form selected from the group consisting of a tablet, a caplet, a capsule, a drug powder and a powder blend, said composition** comprising a therapeutically and/or prophylactically effective amount of celecoxib and a dispersion-enhancing amount of an effervescent agent, wherein (a) the dosage form is adapted for swallowing without prior disintegration in water or in the mouth, and (b) the amount of the effervescent agent is not sufficient to substantially enhance disintegration of the dosage form in an aqueous medium.

Claim 19 (cancelled).

Claim 20 (previously presented): The composition of Claim 18 wherein the rate of dissolution of the celecoxib in an aqueous medium is enhanced.

Claim 21 (original): The composition of Claim 18 wherein the effervescent agent generates oxygen or carbon dioxide gas upon contact with water.

Claim 22 (cancelled).

Claim 23 (original): The composition of Claim 18 wherein the effervescent agent comprises an acid component and a base component.

Claim 24 (original): The composition of Claim 23 wherein the acid component comprises at least one acid selected from the group consisting of citric acid, tartaric acid, malic acid, fumaric acid, adipic acid, succinic acid, acid anhydrides and acid salts thereof, and mixtures thereof.

Claim 25 (original): The composition of Claim 24 wherein the at least one acid is citric acid.

Claim 26 (original): The composition of Claim 23 wherein the base component comprises at least one base selected from the group consisting of carbonate salts, bicarbonate salts, sesquicarbonate salts, and mixtures thereof.

Claim 27 (original): The composition of Claim 26 wherein the at least one base is calcium carbonate.

Claim 28 (original): The composition of Claim 23 wherein the weight ratio of the acid component to the base component in the effervescent agent is about 1:100 to about 100:1.

Claim 29 (original): The composition of Claim 23 wherein the weight ratio of the acid component to the base component in the effervescent agent is about 1:50 to about 50:1.

Claim 30 (original): The composition of Claim 23 wherein the weight ratio of the acid component to the base component in the effervescent agent is about 1:10 to about 10:1.

Claim 31 (original): The composition of Claim 23 wherein the ratio of the acid component to the base component in the effervescent agent is approximately stoichiometric.

Claim 32 (original): The composition of Claim 18 wherein the effervescent agent is present in the composition in an amount of about 1% to about 20% by weight.

Claim 33 (original): The composition of Claim 18 wherein the effervescent agent is present in the composition in an amount of about 2% to about 15% by weight.

Claim 34 (original): The composition of Claim 18 wherein the effervescent agent is present in the composition in an amount of about 3% to about 10% by weight.

Claim 35 (currently amended): **The composition of Claim 18 wherein said** ~~**solid pharmaceutical dosage form comprising a therapeutically and/or prophylactically effective amount of celecoxib and a dispersion-enhancing amount of an effervescent agent, wherein the**~~ dosage form does not exceed about 800 mg in total weight.

Claim 36 (original): The dosage form of Claim 35 wherein said dosage form has a total weight of about 100 to about 750 mg.

Claim 37 (original): The dosage form of Claim 35 wherein said dosage form has a total weight of about 200 to about 700 mg.

Claim 38 (cancelled).

Claim 39 (previously presented): The composition of Claim 35 wherein the rate of dissolution of the celecoxib in an aqueous medium is enhanced.

Claim 40 (original): The composition of Claim 35 wherein the effervescent agent generates oxygen or carbon dioxide gas upon contact with water.

Claim 41 (original): The composition of Claim 35 that is a dosage form selected from the group consisting of a tablet, a caplet, a capsule, a drug powder and a powder blend.

Claim 42 (original): The composition of Claim 35 wherein the effervescent agent comprises an acid component and a base component.

Claim 43 (original): The composition of Claim 42 wherein the acid component comprises at least one acid selected from the group consisting of citric acid, tartaric acid, malic acid, fumaric acid, adipic acid, succinic acid, acid anhydrides and acid salts thereof, and mixtures thereof.

Claim 44 (original): The composition of Claim 43 wherein the at least one acid is citric acid.

Claim 45 (original): The composition of Claim 42 wherein the base component comprises at least one base selected from the group consisting of carbonate salts, bicarbonate salts, sesquicarbonate salts, and mixtures thereof.

Claim 46 (original): The composition of Claim 45 wherein the at least one base is calcium carbonate.

Claim 47 (original): The composition of Claim 42 wherein the weight ratio of the acid component to the base component in the effervescent agent is about 1:100 to about 100:1.

Claim 48 (original): The composition of Claim 42 wherein the weight ratio of the acid component to the base component in the effervescent agent is about 1:50 to about 50:1.

Claim 49 (original): The composition of Claim 42 wherein the weight ratio of the acid component to the base component in the effervescent agent is about 1:10 to about 10:1.

Claim 50 (original): The composition of Claim 42 wherein the ratio of the acid component to the base component in the effervescent agent is approximately stoichiometric.

Claim 51 (original): The composition of Claim 35 wherein the effervescent agent is present in the composition in an amount of about 1% to about 20% by weight.

Claim 52 (original): The composition of Claim 35 wherein the effervescent agent is present in the composition in an amount of about 2% to about 15% by weight.

Claim 53 (original): The composition of Claim 35 wherein the effervescent agent is present in the composition in an amount of about 3% to about 10% by weight.

Claims 54-61 (Cancelled).

REMARKS

STATUS OF THE CLAIMS

Claims 18, 20-37, and 39-53 are currently pending and stand rejected under 35 U.S.C. §103(a) as being obvious over Bolt et al., European Patent No. 396 335 ("Bolt") in view of Harrison et al., U.S. Patent No. 6,086,909 ("Harrison").

Claims 18 and 35 have been amended and claim 22 has been cancelled. Claim 18 has been amended to incorporate the limitations of dependent claim 22. Claim 35 has been amended to depend from claim 18. Support for this amendment may be found, for example, at page 3, lines 30-32 of the specification. No new matter has been added by these amendments.

REJECTION OF CLAIMS 18, 20-37, and 39-53 UNDER §103(a)

Reconsideration is respectfully requested of the rejection of claims 18, 20-37, and 39-53 under §103(a) as being obvious over Bolt in view of Harrison.

Claim 22 has been cancelled, rendering moot its rejection under §103(a).

Claim 18, as amended, is directed to a solid pharmaceutical composition that is a dosage form selected from the group consisting of a tablet, a caplet, a capsule, a drug powder and a powder blend, said composition comprising a therapeutically and/or prophylactically effective amount of celecoxib and a dispersion-enhancing amount of an effervescent agent, wherein (a) the **dosage form is adapted for swallowing without prior disintegration in water or in the mouth**, and (b) the amount of the effervescent agent is not sufficient to substantially enhance disintegration of the dosage form in an aqueous medium. (emphasis added)

Bolt, on the other hand, describes pharmaceutical compositions – in particular, **chewable tablets** – for oral administration of antibiotics and other medicaments with unpleasant taste characteristics. Indeed, Bolt specifically teaches away from dosage forms adapted for swallowing without prior disintegration in water or in the mouth:

> Solid dosage forms which are swallowed, such as tablets and capsules, provide accurate dosage and avoid taste problems; but since they have to disintegrate in the gastrointestinal tract and the medicament has then to dissolve before it can be absorbed, absorption tends to be slower than from a suspension, and may be less than complete. Also, some patients have difficulty swallowing tablets and capsules, and there is a practical limit to the size, and therefore the dose, that can be swallowed.

...

> In general, chewable tablets are advantageous in that they combine the accuracy of dosage associated with tablets, with the optimum bioavailability of suspensions.
>
> **Page 2, lines 9-13 and 19-20.**

In addition to the above-cited language, Bolt describes in great detail the technologies necessary to taste-mask the medicament with unpleasant taste characteristics. See, e.g., pages 2 and 3. Certainly, such taste masking would not be necessary in a solid pharmaceutical composition adapted for swallowing without prior disintegration in water or in the mouth, such as the composition of claim 18.

Bolt teaches away from the claimed invention. Harrison describes a vaginal drug delivery system, and mentions that COX-2 inhibitors such as celecoxib, meloxicam, and flosulide are anti-inflammatory and analgesic compounds. Nowhere does Harrison describe or suggest the composition of claim 18.

For the foregoing reasons, claim 18 is patentable over Bolt and Harrison. Similarly, dependent claims 20, 21, 23-37, and 39-53 are also patentable for the same reasons, and for the additional features they add.

CONCLUSION

The Applicants submit that the present invention is now in condition for allowance. Early allowance of all pending claims is respectfully solicited.

Respectfully submitted,

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